IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al., | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION, | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8957**

Bartle, J. November 6, 2012

Nancy I. Graves ("Ms. Graves" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Michael R. Graves, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust he has signed in excess of 318 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated May 11, 2001, Dr. Evans attested in Part II of claimant's Green Form that Ms. Graves suffered from moderate mitral regurgitation and an abnormal left atrial

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

dimension.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $528,405.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Michelle R. Brown, M.D., F.A.C.C., stated that claimant had "1-2+ mitral insufficiency ...."[6] Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In June, 2005, the Trust forwarded the claim for review by Robert A. Skotnicki, D.O., F.A.C.C., F.S.C.A.I., one of its auditing cardiologists. In audit, Dr. Skotnicki concluded that

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4. Dr. Evans also attested that claimant did not suffer from mitral annular calcification. Under the Settlement Agreement the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Given our disposition regarding claimant's level of mitral regurgitation, however, we need not address whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. Claimant also submitted an echocardiogram report prepared in June, 2002 by Dr. Evans based on her May 11, 2001 echocardiogram. In this report Dr. Evans stated that claimant had "[m]oderate mitral regurgitation. The RJA/LAA ratio is 22%."

there was no reasonable medical basis for the attesting physician's finding that Ms. Graves had moderate mitral regurgitation. In support of this conclusion, Dr. Skotnicki stated:

> There is a regurgitant jet of [mitral regurgitation] seen in the [parasternal long-axis] view. From this view alone, considering the Nyquist limit settings, the [mitral regurgitant jet] does not appear to occupy more than 10-15% of the LAA. However that view is not the view stipulated on the Green Form but can help substantiate the presence of [a mitral regurgitant] jet. In the apical view, [mitral regurgitant] jet is barely visible. There is no planimetry of the left atrium or a [mitral regurgitant jet] in this view. Even though, there is a ratio presented on the re-dictated form. These values cannot be verified nor do they appear medically reasonable.

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant submitted an affidavit from Dr. Evans, who confirmed his previous finding that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 22%. Claimant argued that

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

the affidavit of Dr. Evans provided a reasonable medical basis to support her claim. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his **personal opinion** ... and the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On November 3, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5833 (Nov. 3, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 10, 2006, and claimant submitted a sur-reply on January 27, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer at issue in claimant's Green Form, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Graves repeats the arguments made in contest: namely, that the affidavit of Dr. Evans provides a reasonable medical basis for the claim.

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8. (...continued)
are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Claimant also contends that the concept of inter-reader variability accounts for the difference between the opinions of the attesting physician and the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Graves contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the opinion of the attesting physician does not establish a reasonable medical basis for her claim because Dr. Evans does not address Dr. Skotnicki's finding that claimant had only mild mitral regurgitation. The Trust also notes that Dr. Evans does not address the original echocardiogram report prepared by Dr. Brown, which indicates that claimant did not have moderate mitral regurgitation. The Trust further contends that inter-reader variability does not establish a reasonable medical basis for the claim because Dr. Skotnicki specifically determined that there was no reasonable medical basis for the findings of Dr. Evans.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Graves had moderate mitral regurgitation. Specifically, Dr. Vigilante found that:

> A thin jet of mitral regurgitation was noted in the parasternal long axis view. Excessive color gain with a low Nyquist limit was found in the apical views. Color flow artifact could be seen in the myocardium. In spite of this abnormal gain, I was able to accurately determine the severity of mitral regurgitation on this study. Visually, only mild mitral regurgitation was present in the apical 4-chamber and apical two chamber views. I digitized those cardiac cycles in the apical views in which the mitral regurgitation appeared most severe. I then measured the RJA and LAA in these cardiac cycles. The RJA/LAA ratio was less than 11% in those views in which the mitral regurgitation jet appeared most severe. The RJA/LAA ratio never came close to approaching 20%. Most of the cardiac cycles demonstrated RJA/LAA ratios of less than 10%. My findings correspond with those of Dr. Brown, the original interpreting echocardiographer.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, claimant does not adequately refute the conclusions of the auditing cardiologist and the Technical Advisor. Claimant does not rebut the auditing cardiologist's determination that "[i]n the apical view, [mitral regurgitant] jet is barely visible."[9] Nor does she challenge the Technical Advisor's conclusion that "only mild mitral regurgitation was present in the apical 4-chamber and apical two chamber views" or that "[t]he RJA/LAA ratio was less than 11% in those views in which the mitral regurgitation jet appeared most

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9. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his opinion for the diagnosis of the attesting physician.

severe."[10] Neither claimant nor her attesting physician identified any particular error in the conclusions of the auditing cardiologist and the Technical Advisor. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Moreover, we disagree with claimant that the affidavit of Dr. Evans establishes a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here,

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10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Dr. Skotnicki determined that "the Nyquist limit is set very low at 46." Similarly, Dr. Vigilante observed that "[e]xcessive color gain with a low Nyquist limit was found in the apical views. Color flow artifact could be seen in the myocardium." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Graves had moderate mitral regurgitation is misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrated RJA/LAA ratios of less than 11% and the auditing cardiologist determined that claimant had, at most, mild mitral regurgitation. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by ±15% would allow a claimant to recover benefits with a RJA/LAA as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[11]

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11. Moreover, the Technical Advisor specifically took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably

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For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Graves for Matrix Benefits and the related derivative claim submitted by her spouse.

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11. (...continued)
conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."